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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/707,087	11/20/2003	Muhammed Majeed		1086

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EXAMINER	
KWON, BRIAN YONG S	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/707,087	MAJEED ET AL.	
	Examiner	Art Unit	
	Brian S. Kwon	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5 and 8-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 5, 8-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. By Amendment filed May 02, 2006, claims 1-3, 5 and 8-9 have been amended, claim 4 has been cancelled, and claim 10 has been newly added. Claims 1-3, 5, 8-10 are currently pending for prosecution on the merits.

Summary of Action

2. The rejection of the claims 1-3 and 59 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of USP 5,804,596 in view of De Souza is not maintained in light of approved Terminal Disclaimer filed May 02, 2006.

3. The rejection of the claim 4 under 35 U.S.C. 112, first paragraph, is not maintained in light of the amendment.

4. The rejection of the claims 1-9 under 35 U.S.C. 112, second paragraph, is not maintained in light of the amendment.

5. The rejection of the claims 1-9 under 35 U.S.C.103(a) as being unptatentable over Majeed et al. (USP 5,804,596) in view of De Souza ("Industrial Development of Tranditional Drugs: The Forskolin Example a Mini-Review", Journal of Ethnopharmacology, Vol. 38, No. 2-3, pp. 167-175, 2003), and further in view of Sears et al. (USP 4,476,140), Morazzoni et al. (USP 5,902,823), Greenway, III et al. (USP 4, 525,359) and Majeed et al. (USP 6,960,300) is maintained for the reasons of record.

6. Applicant's amendment, particularly step(s) in claims 5, 8-10, necessitates a new ground of rejection in this Office Action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-3, 5, 8-10 are rejected under 35 U.S.C.103(a) as being unptatentable over Majeed et al. (USP 5,804,596) in view of De Souza ("Industrial Development of Tranditional Drugs: The Forskolin Example a Mini-Review", Journal of Ethnopharmacology, Vol. 38, No. 2-

3, pp. 167-175, 2003), and further in view of Sears et al. (USP 4,476,140), Morazzoni et al. (USP 5,902,823), Greenway, III et al. (USP 4, 525,359) and Majeed et al. (USP 6,960,300)

Majeed teaches a method of promoting lean body mass in an individual with administering of a lean body mass promoting effective amount of forskolin (see abstract). Note the forskolin composition is from a forskolin extract of Coleus Forskohlii plant. Note particularly column 4, lines 23-25 shows the dose of from about 10 to about 60mg (applicant's claim 2 dose falls within the range). Note column 4, lines 55-67 and columns 5 and 6 show the preparation of forskolin extract in process of conventional solvent extraction and purifications based on differential solubility in organic solvents.

The instant invention differs from the cited reference in (i) the use of isoforskolin and/or deacetytforskolin for the treatment of obesity and promote lean body mass, (ii) the specific dosage forms (e.g., tablets, capsules, powders, ready-to mix preparations, spansules, chewable, liquids, solutions, suspension, beverage drinks, carbonated drinks, emulsions, or topical), and (iii) the specific extraction steps of preparing said composition by "pulverizing the roots of Coleus forskohlii or related species; extracting the roots with a solvent selected from C1-C4 alcohols, toluene, or hexane; treating the extract with an immobilized preparation of lipase enzyme at a concentration of 0.1%-10% w/v at 37°C for 12 hours with agitation; filtering the extract and back extraction of the filtrate with aqueous alcohol in a water: alcohol ratio ranging from 10:90 to 90:10; and crystallization of 7-deacetylforskolin from the extract in alcohol". However, the secondary reference, De Souza, teaches extracts from plants such as Coleus forskohlii containing forskolin is reported to contain lad bane diterpenes like isoforskolin and deacetytforskolin. Clearly, one skilled in the art would have assumed that isoforskolin and

deacetytforskolin possesses the same activity as forskolin. Therefore, to substitute isoforskolin in place of forskolin will promote the same lean body mass effective amount in the absence of evidence to the contrary.

With respect to the determination of the specific dosage forms including tablets, capsules, powders, ready-to mix preparations, spansules, chewable, liquids, solutions, suspension, beverage drinks, carbonated drinks, emulsions and topical, tertiary references (Sears teaches forskolin in a topical suspension; Greenway teaches forskolin as a weight control agent in topical applications; Morazzoniet teaches forskolin can formulated into tablets; Majeed'300 who teaches diterpenes such as forskolin and its congeners, analogs and derivatives can be formulated into topical and systemic use as pharmaceutical, cosmeceuitcal and neutraceutical preparations) show the various modes of administration that forskolin, which contains isoforskolin, can be formulated into the desired formulation without undue amount of experimentation.

Although the instant claims are defined by the specific limitation of the process extracting, the patentability of the instant claim is not dependent upon the manner in which is produced. Thus, the prior art references in combination (particularly Majeed'596 who teaches the use of (same) forskolin composition extracted from Coleus Forskohlii plant by the conventional solvent extraction and purifications based on differential solubility in organic solvents) make obvious the instant invention.

Response to Arguments

8. No argument is present in the applicant's Response filed May 02, 2006. In absence of the applicant's "Remarks" pointing out disagreements with the examiner's contentions, the examiner maintains that the instant invention is obvious over the cited references in combination. .

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. No Claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718. The fax number for this Group is (571) 273-8300.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see http://pair-direct.uspto.gov Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Brian Kwon
Primary Patent Examiner
AU 1614